REMARKS

The Office action mailed January 13, 2005 has been received and reviewed. Claims 1 through 21 were pending in the application. Claims 1 through 11 and 21 have been withdrawn from consideration. The patent application is to be amended as previously set forth. Claim 20 is to be canceled. New claims 22 through 25 are to be added. All amendments and claim cancellations are made without prejudice or disclaimer. Basis for the amendments to claim 12 and new claim 22 is found in paragraph 15 of the application as filed. No new matter has been added. Reconsideration is respectfully requested.

A. Amendments to the specification:

The application is to be amended to update the priority claim, and to identify specifically that the patent application from which this application claims priority has issued as U.S. Patent 6,878,375. In a related vein, the Office action indicated that the priority documents had not yet been received. Since the requested documents have been provided in the parent application, no further action should be required of applicants and the priority claim should be perfected.

B. 35 U.S.C § 112, first paragraph:

Claims 12-20 were objected to as the specification allegedly was insufficient to provide enablement and written description support beyond a process for producing minor histocompatibility antigen HA-1 specific cytotoxicity T cell providing an isolated, synthetic or recombinant peptide of SEQ ID NO:1, and contacting an APC with the peptide, thus producing the cytotoxic T cell. (Office Action, pp. 2-3). Specifically, the claims were thought too broad to the extent they extended to any "minor antigen", to any peptide "comprising" SEQ ID NO:1, to any "suicide gene", and to any cytotoxic T cell. Applicants have amended independent claim 12, and partially in view of the amendment, request that the rejections under the first paragraph of 35 USC § 112 be withdrawn.

It is submitted that the current set of claims meets all of the requirements of the first paragraph of 35 U.S.C. § 112. The specification provides sufficient enablement and written description for a method for producing CTL against mHag HA-1. Moreover, amended claim 12

and new claim 21 more specifically define a peptide according to the invention.

Specifically, amended claim 12 refers to a peptide having up to 15 amino acids. Basis for this amendment can be found on paragraph 15 of the patent application as-filed.

Claim 12 has furthermore been amended in order to more specifically define how a CTL is produced using an antigen presenting cell. Basis for this amendment can be found on paragraph 25 of the patent application as filed. Reconsideration of the objections is thus requested.

Claim 16 was objected to for use of the phrase "suicide gene". It is however submitted that suicide genes were well known to those of skill in the art at the priority date of the present application and further elucidation would be unnecessary. As stated in the MPEP, a "patent specification is not intended nor required to be a production specification" (MPEP § 608.01(h)). "Furthermore, a patent need not teach, and preferably omits, what is well known in the art" *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986) (*citing Lindemann Maschinenfabrik v. American Hoist and Derrick,* 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984)).

Likewise, one of the *Wands* factors is the skill level of one of the ordinarily skilled artisan. For this invention, the skill level would clearly be quite high. One of such high skill would understand the meaning of the term "suicide gene" and, accordingly, be enabled to utilize applicants' disclosure. For instance, Goulmy et al., Human Immunology, 54:8-14 (April 1997) (cited against the application in the Office Action at item 13), discloses the use of a suicide gene on page 12, lines 20- 22. Further, a well-known example of a suicide gene is a gene encoding the thymidine kinase of herpes simplex virus, which is identified and specifically referenced in the patent application at page 18, lines 6-8 of the application as filed, *i.e.*, cited reference 41. "Bonini, C. *et. al.* HSV-TK gene transfer into donor lymphocytes for control of allogeneic graft-versus-leukemia [see comments]. *Science* 276: 1719-1724. (1997)."[1] Accordingly, applicants believe they have already complied with the first paragraph of 35 U.S.C. § 112 in this regard.

Reconsideration of the objection is thus requested.

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[1] Accordingly, new dependent claim 25 is presented identifying this specific gene.

C. 35 U.S.C. 112, second paragraph

Claims 12 through 18 and 20 are rejected as assertedly being indefinite. Applicants have amended independent claim 12, and partially in view of the amendment, request that the rejections be withdrawn.

Specifically, applicants have amended claim 12 to more clearly delineate steps of the claimed method (e.g., "pulsing an antigen presenting cell with the isolated, synthetic or recombinant peptide; and contacting a hematopoietic cell with the ~~isolated, synthetic or recombinant peptide~~ antigen presenting cell, thus, producing the cytotoxic T-cell." (Underlining and strike out in original).

Applicants traverse the remainder of the rejection, however, as to include the further elements would unduly affect applicants' claims. Applicants have fully complied with the second paragraph of 35 U.S.C. § 112 in providing clear, definite claims. No more is required.

D. 35 U.S.C. 103(a)

Claims 12-16 and 18-20 are rejected by the examiner as allegedly being unpatentable under 35 U.S.C. § 103 over Bakker et al. in view of Goulmy, and Den Haan (or Van der Haan) et al. (Science 279: 1054-57, Feb.1998) or Nagase et al.

Den Haan et al. was published in 1998, which is after the priority date of the current application. Den Haan et al. is therefore not a prior art reference to the present application. As previously stated with regard to the updated priority claim, the priority documents were submitted in the parent (granted) patent application. Nothing further should be required of applicants.

Continuing, Bakker et al., Goulmy, and Nagase et al. do not disclose a peptide having up to 15 amino acids comprising the sequence VLXDDLLEA. Applicants were unable to find an antigen comprising QCG . .VLRDDLLEA . . . EFV in Nagase et al. (Cf., Office Action, page 8, third paragraph). Further direction or clarification is respectfully requested. It is neither shown nor suggested by any of these references that a cytotoxic T-cell against mHag HA-1 can be produced using a peptide having up to 15 amino acids comprising the sequence VLXDDLLEA as

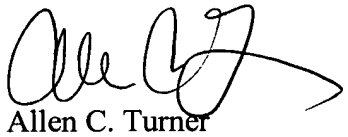
claimed in claim 12. Hence, any combination of Bakker et al., Goulmy and/or Nagase et al. would not render the subject matter of current claims 12-21. Claims 12-21 are therefore not obvious.

Claim 17 is rejected as allegedly being unpatentable over Bakker et al. (Cancer Res 55(22): 5330.4, 1995) in view of Goulmy (Human Immunology 54: 8-14, 1997), Den Haan et al. (Science 279: 1054-57, 1998) or Nagase et al (DNA res 3(5): 321-329, 1996) and further in view of Faller et al. (J Virology 62(8): 2942-2950, 1988).

However, as previously shown, claims 12-21 are inventive over any combination of Bakker et al., Goulmy, and/or Nagase et al. (while Den Haan et al. is not prior art to the present application). Since claim 17 is dependent on inventive claim 12, claim 17 also involves an inventive step.

The claims should now be in condition for allowance. If, however, questions remain after consideration of the foregoing, the Office is kindly requested to contact applicants' attorney at the address or telephone number given herein.

Respectfully submitted,



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Date: June 13, 2005